

REMARKS

The Final Office action dated January 28, 2010 is acknowledged. Claims 1-27 are pending in the instant application. According to the Final Office action, claims 1-4, 6-8, 13-15, 18, 19 and 23-27 have been rejected and claims 10-12, 16, 17 and 20-22 have been withdrawn. By the present response, claims 1-4, 6-8 and 10-27 have been canceled and claims 28-48 have been added, support for which may be found throughout the specification as discussed below. As discussed with the Examiner by telephone on April 16, 2010, the filing of the RCE with the new set of claims is deemed proper. It is noted that the new claims recite subject matter of the withdrawn claims, i.e., a therapeutic system having at least three layers.

Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 1-4, 6-8, 13-15, 18, 19 and 23-27 under double patenting

Claims 1-4, 6-8, 13-15, 18, 19 and 23-27 have been provisionally rejected under the obviousness-type double patenting doctrine as being unpatentable over claims 1-4 and 7-9 of co-pending Application No. 11/408,958 in view of Rault, et al. and Ruprecht (both discussed below). The Examiner argues that the present claims are not patentably distinct from those of '958 because the scope of the '958 claims renders obvious that of the instant claims. The Examiner states that the difference between the two claim sets is that the '958 claims recite rapid release from one layer and slow release from another layer. However, the Examiner's position is that this element – and thus the entire scope of the

instant claims – is rendered obvious since the instant claim 14 recites at least two layers containing an active substance at different concentrations.

In view of the cancellation of claims 1-4, 6-8, 13-15, 18, 19 and 23-27, it is submitted that the provisional rejection under the obviousness-type double patenting doctrine is now moot. Withdrawal is thus requested.

Rejection of Claims 1-4, 6-8, 13-15, 18, 19 and 23-27 under 35 U.S.C. 103(a)

Claims 1-4, 6-8, 13-15, 18, 19 and 23-27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over various prior art references. In view of the cancellation of these claims, it is submitted that the rejection is now moot and thus withdrawal is appropriate.

It is additionally submitted that the combination of teachings of the cited prior art references fail to teach each and every limitation of new claims 28 – 48 and that it would have not been obvious for one skilled in the art to have combined or otherwise modified the prior art teachings to arrive at the presently claimed invention. New independent claim 28 recites a film-shaped therapeutic system comprising at least three layers. Regarding the three-layer configuration, the backing layer is (at least) a double-layer (see, for example, paragraphs [000016], [000020], [000025], [000036], [000038] – [000041] and [000048] – [000056]; Figure 2, of the present specification). Regarding “neutralized polymethyl methacrylate,” support may be found in the specification, such as at paragraph [000025].

New independent claim 28 also recites that the backing layer contains an active substance and a pigment (see, for example, paragraphs [000025], [000039] and [000040] of the present specification) and that one layer of the two-layered backing layer does not

contain pigment or contains a lower portion of the pigment than is contained in the respective other layer of the double layer (see, for example, paragraphs [000039] and [000053] of the present specification).

Regarding the mucoadhesive layer, new claim 28 recites that the layer contains a polymer mixture comprising polyvinyl alcohol as well as a mucoadhesive polymer selected from the group consisting of poly(methyl vinyl ether maleic anhydride), aqueous hydrolysates of poly(methyl vinyl ether maleic anhydride), alcoholic hydrolysates of poly(methyl vinyl ether maleic anhydride) and salts of poly(methyl vinyl ether maleic anhydride) (see, for example, paragraphs [000018] and [000054] of the present specification).

New independent claim 29 recites, as set forth in the Example (paragraph [000053]), that one of the layers of the two-layered backing layer contains a lower portion of the pigment than is contained in the respective other layer (i.e., “a second liquid is prepared which differs from the first formulation only in that it does not contain the pigment or contains a lower portion of pigment”).

Support for the remaining new claims can be found in the present specification as follows:

Claim 30 – Paragraph [000017], reciting “optionally, the mucoadhesive layer may contain active substance.”

Claim 31 – Paragraph [000019].

Claim 32 – Paragraph [000039].

Claim 33 – Paragraph [000018].

Claim 34 – Paragraph [000018]. It is noted that CARBOPOL® of the referenced paragraph relates to polymers of acrylic acid crosslinked with allyl sucrose or allyl pentaerythritol.

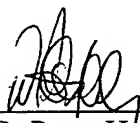
Claim 35 – Paragraph [000023]; Claim 36 – Paragraph [000034]; Claim 37 – Paragraph [000036]; Claim 38 – Paragraphs [000030] and [000051]; Claim 39 – Paragraph [000056]; Claim 40 – Paragraph [000021]; Claim 41 – Paragraph [000040]; Claim 42 – Paragraph [000040]; Claim 43 – Paragraph [000054]; Claim 44 – Paragraph [000054]; Claim 45 – Paragraph [000039] and Claims 46 – 48 – Paragraphs [000025] – [000029].

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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By: 
D. Peter Hochberg
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.
1940 East 6th Street, 6th Floor
Cleveland, OH 44114
(216) 771-3800